

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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WRITTEN OPINION OF THE  
INTERNATIONAL PRELIMINARY  
EXAMINING AUTHORITY

(PCT Rule 66)

DUE DATE:	27-MAY-2006
FORMALITIES:	C.N   R.P.4
PAT OFF:	A.K ✓
ON DB	30/3/06
CASE NO.	PU0460-PCT

Date of mailing  
(day/month/year)

28-03-2006

Applicant's or agent's file reference

PU0460-PCT ✓

REPLY DUE

within 60 days from  
the above date of mailing

International application No.

PCT/SE2005/000293 ✓

International filing date (day/month/year)

25-02-2005 ✓

Priority date (day/month/year)

27-02-2004

International Patent Classification (IPC) or both national classification and IPC

See Supplemental Box

Applicant

AMERSHAM BIOSCIENCES AB et al

- ☒ The written opinion established by the International Searching Authority:  
☒ is ☐ is not  
considered to be a written opinion of the International Preliminary Examining Authority.
- This second (first, etc.) opinion contains indications relating to the following items:
  - ☒ Box No. I Basis of the opinion
  - ☐ Box No. II Priority
  - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - ☐ Box No. IV Lack of unity of invention
  - ☒ Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Box No. VI Certain documents cited
  - ☐ Box No. VII Certain defects in the international application
  - ☐ Box No. VIII Certain observations on the international application
- The applicant is hereby invited to reply to this opinion.

**When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(e).

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis. For an informal communication with the examiner, see Rule 66.6. For an additional opportunity to submit amendments, see Rule 66.4.

**If no reply is filed,** the international preliminary examination report will be established on the basis of this opinion.
- The final date by which the international preliminary report on patentability (Chapter II of the PCT) must be established according to Rule 69.2 is: 27-06-2006

Name and mailing address of the IPEA/SE

Patent- och registreringsverket  
Box 5055  
S-102 42 STOCKHOLM

Facsimile No. 46 8 667 72 88

Form PCT/IPEA/408 (cover sheet) (April 2005)

Authorized officer

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**WRITTEN OPINION OF THE  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY**

International application No.

**PCT/SE2005/000293**

**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Cover sheet**

**International patent classification (IPC)**

**B01D 15/18 (2006.01)**

**B01D 15/32 (2006.01)**

**B01D 15/36 (2006.01)**

**B01J 39/04 (2006.01)**

**C07K 16/06 (2006.01)**

WRITTEN OPINION OF THE  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.

PCT/SE2005/000293

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of:



the international application in the language in which it was filed



a translation of the international application into \_\_\_\_\_,  
which is the language of a translation furnished for the purposes of:



international search (Rules 12.3(a) and 23.1(b))



publication of the international application (Rule 12.4(a))



international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this opinion has been established on the basis of (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."*):



the international application as originally filed/furnished



the description:

pages \_\_\_\_\_ as originally filed/furnished

pages \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages \_\_\_\_\_ received by this Authority on \_\_\_\_\_



the claims:

pages \_\_\_\_\_ as originally filed/furnished

pages \_\_\_\_\_ as amended (together with any statement) under Article 19

pages \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages \_\_\_\_\_ received by this Authority on \_\_\_\_\_



the drawings:

pages \_\_\_\_\_ as originally filed/furnished

pages \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages \_\_\_\_\_ received by this Authority on \_\_\_\_\_



a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:



the description, pages \_\_\_\_\_



the claims, Nos. \_\_\_\_\_



the drawings, sheets/figs \_\_\_\_\_



the sequence listing (*specify*): \_\_\_\_\_



any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).



the description, pages \_\_\_\_\_



the claims, Nos. \_\_\_\_\_



the drawings, sheets/figs \_\_\_\_\_



the sequence listing (*specify*): \_\_\_\_\_



any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

WRITTEN OPINION OF THE  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT/IS2003/000299

**Box No. V** Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

**1. Statement**

Novelty (N)	Claims	<u>1-3, 6-8, 15</u>
	Claims	<u>17 and 23-25 (no)</u>
Inventive step (IS)	Claims	<u>1-25 (no)</u>
	Claims	_____
Industrial applicability (IA)	Claims	_____
	Claims	_____

**2. Citations and explanations:**

The following documents are considered relevant:

D1) Johansson B-L, "Preparation and characterization of prototypes for multimodal separation aimed for capture of positively charged biomolecules at high-salt conditions", 2003, vol 1016 page 35-49 Journal of Chromatography A.

D2) BLANK GS, ET AL.: "Expanded bed absorption in the purification of monoclonal antibodies: a comparison of process alternatives." 2001, vol. 10, pages 65-71 BIOSEPARATION,

D1 discloses a process for purifying antibodies using a multimodal separation material which is a cation-exchange resin with aromatic ring systems where the ring-forming atoms can be carbon, sulphur or oxygen, see table 2, figure 3 and the whole document. It is stated that the resin should be tested for capture proteins from different feedstocks.

Consequently, the subject matter of claims 1-3, 6-8, 15, 17 and 23-25 is previously known and therefore lacks novelty.

Document D1 is considered to represent the closest prior art. The invention according to claims 4-5, 9-12, 14, 16, 18-22 differs from the process in D1 in that it has an additional purification step thereby obtaining antibodies with higher purity.

Consequently, with the background of D1, the problem is to design a process that obtains antibodies with higher purity. It is well established in the art of protein purification in general, as well as for antibodies, to use an additional

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International application No.

PCT/SE2005/000293

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

chromatography step in purification. Hence, a person skilled in the art would seriously consider additional chromatography steps when purifying antibodies with the resin of D1. Therefore, the invention according to claims 4-5, 9-12, 14, 16, 18-22 lacks an inventive step.

Claim 13 is directed to a process using a second chromatography step in a flow through manner. Such chromatography has been applied on immunoglobulins, see e.g. D2. Therefore, a person skilled in the art would include said method among the methods considered in the second step - see previous reasoning concerning claim 4 etc.

Therefore, the invention according to claim 13 lacks an inventive step.